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SECTION 14

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Genyx Medical, Inc.
66 Argonaut, Suite 170
Aliso Viejo, CA 92656

b. Contact Person: Judy F. Gordon, D.V.M.

c. Date Summary Prepared: March 24, 2000

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Genyx Flexible Injection Needle

b. Classification Name: Endoscope Needle

3. Identification of the predicate devices or legally marketed devices or devices to which substantial equivalence is being claimed:

Company:	Genyx Medical, Inc.	C.R. Bard, Inc.
Device:	Genyx Injection Needle	Bard Flexible Endoscopy Injection System
510(k):	K990996	K970110
Date Cleared:	3/24/99	02/19/97

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Genyx Flexible Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure. The Genyx Flexible Injection Needle materials are similar to those used in the predicate device.

5. Statement of intended use:

The Genyx Flexible Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The Genyx Flexible Injection Needle is substantially equivalent to both predicate devices. They all contain a stainless steel piercing tips, a polymer or a stainless steel body portion and a luer lock hub where a standard syringe can be attached for injection of materials through the lumen of the needle into tissue.

7. Brief summary of nonclinical tests and results:

The Genyx Flexible Injection Needle has been designed and will be tested to applicable safety standards. In addition, the Genyx Flexible Injection Needle was found to perform equivalently to the predicate device, the Genyx Injection Needle with respect to injection performance. Thus, the technological changes in the Genyx Flexible Injection Needle do not raise any new issues of safety, effectiveness or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

Judy F. Gordon, D.V.M.
Vice President, Clinical and
Regulatory Affairs
Genyx Medical, Inc.
66 Argonaut, Suite 170
Aliso Viejo, CA 92656

Re: K001146
Genyx Flexible Injection Needle
Dated: April 7, 2000
Received: April 10, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FBK

Dear Dr. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION 6

INDICATIONS FOR USE

The Genyx Flexible Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

Prescription Use

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001146